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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,275	07/18/2003	Tilak M. Shah	4179-123	4204

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER
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WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/622,275	SHAH, TILAK M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-51 is/are pending in the application.
- 4a) Of the above claim(s) 16-28, 40-42, 45-49 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 29-39, 43, 44 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4,6,9,12-14,29-32,34-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stambaugh (USPN 6,136,011) in view of Lentz et al (USPN 4,668,224).

Stambaugh discloses a double balloon catheter. The balloons are concentric. Two non-concentric inflation lumens extend from the proximal end of the catheter to the balloons. See figure 2. Stambaugh does not disclose a hemostatic material coated on the second balloon.

However, at the time of the invention, it would have been obvious to coat the catheter including the second balloon with oxidized cellulose as taught by Lentz. Lentz discloses that the oxidized cellulose is used as a lubricant to make introduction of the device easier. Additionally, the material is biodegradable. Since the instant specification teaches that oxidized cellulose is one of the preferred hemostatic agents it is inherently capable of reducing hemorrhage of the body cavity.

Claims 1-5,8,10,12-14,29-33,36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty (USPN 4,338,942) in view of Lentz. Fogarty discloses a double balloon catheter. The balloons are concentric. Two concentric inflation lumens extend from the

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proximal end of the catheter to the balloons. See figures 2,4. Fogarty does not disclose a hemostatic material coated on the second balloon.

However, at the time of the invention, it would have been obvious to coat the catheter including the second balloon with oxidized cellulose as taught by Lentz. Lentz discloses that the oxidized cellulose is used as a lubricant to make introduction of the device easier. Additionally, the material is biodegradable. Since the instant specification teaches that oxidized cellulose is one of the preferred hemostatic agents it is inherently capable of reducing hemorrhage of the body cavity.

Claims 1-4,6-8,12-14,29-32,34-36,43-44,50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al (USPN 6,746,465) in view of Lentz. Diederich discloses a double balloon catheter. The balloons are concentric. Two non-concentric inflation lumens extend from the proximal end of the catheter to the balloons. See figure 8. Dieterich does not disclose a hemostatic material coated on the second balloon.

However, at the time of the invention, it would have been obvious to coat the catheter including the second balloon with oxidized cellulose as taught by Lentz. Lentz discloses that the oxidized cellulose is used as a lubricant to make introduction of the device easier. Additionally, the material is biodegradable. Since the instant specification teaches that oxidized cellulose is one of the preferred hemostatic agents it is inherently capable of reducing hemorrhage of the body cavity.

Claims 11 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stambaugh, Fogarty or Diederich all in view of Lentz in further view of Wang et al (USPN

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5,512,051). Stambaugh, Fogarty and Diederich each in view of Lentz independently meet the claim limitations as described above but each fail to teach a friction reducing coating between the balloons.

However, Wang teaches such a friction reducing coating. The coating aids in the inflation/deflation of the balloons.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate the friction reducing coating as taught by Wang into either or all of Stambaugh, Fogarty or Diederich all in view of Lentz. The motivation for the incorporate is provided by Wang in that the coating enhances the inflation/deflation ability of the balloons. One skilled in the art would recognize the advantage of the coating in order to make the device easier for a physician to use during a procedure.

### *Response to Arguments*

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
May 30, 2006